DEC - 1 2004

510(K) SUMMARY

Laparoscopic Compression Anastomosis Clip (LapCAC)

510(k) Number K043115

Applicant's Name:

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And/or

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Date Prepared:

November, 2004

Trade Name:

Laparoscopic Compression Anastomosis Clip (LapCAC)

Classification Name:

IMPLANTABLE CLIP

Classification:

The FDA has classified implantable clip as class II device (product code FZP, Regulation No. 21 C.F.R. § 878.4300) and they are reviewed by the Division of General and Restorative Devices.

Predicate Device:

- **CAC, Compression Anastomosis Clip** (NiTi Medical Technologies Ltd.) cleared under K033324.
- **CAC, Compression Anastomosis Clip** (NiTi Medical Technologies Ltd.) cleared under K041751.
- **Endo GIA Universal Stapler System** (United States Surgical Cooperation, USA) originally cleared under K892233 and K913802.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Intended Use:

The NiTi Laparoscopic Compression Anastomosis Clip (LapCAC) is intended to be used to facilitate side-to-side anastomosis of the alimentary tract yielding an inverted serosa-to-serosa anastomosis. Once wound strength is sufficient to maintain the anastomosis, the NiTi Clip is passed from the body. The LapCAC is indicated for open, minimally invasive or laparoscopic procedures.

Device Description:

The Laparoscopic Compression Anastomosis Clip (LapCAC) device is a sterile single patient use device. The LapCAC provides a simple method for the creation of side-to-side compression anastomosis of the alimentary tract in open, minimally invasive and laparoscopic procedures. The LapCAC device is comprised of two components:

- Clip Reload – double ring clip that is inserted into the two cut segments of the tissue to be anastomosed and performs the required compression on the tissue.

- Applier/Handle - with which the Clip is introduced into the treated area.
  The LapCAC device has an extended 35 or 45 cm. long shaft and is designed to pass through a 12 mm standard trocar.

After a period of 7-10 days, a compression-induced necrosis of the tissue sides underneath the rings occurs and the whole device, together with the necrosed tissue that was compressed by the rings, detaches and is naturally expelled with the stool.

Substantial Equivalence:

Based on performance testing results NiTi Medical Technologies Ltd. believes that the Laparoscopic Compression Anastomosis Clip (LapCAC) is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

NiTi Medical Technologies Ltd
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K043115
Trade/Device Name: Laparoscopic Compression Anastomosis Clip (LapCAC)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: November 4, 2004
Received: November 10, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043115

Device Name: Laparoscopic Compression Anastomosis Clip (LapCAC)

Indications for Use:

The NiTi Laparoscopic Compression Anastomosis Clip (LapCAC) is intended to be used to facilitate side-to-side anastomosis of the alimentary tract yielding an inverted serosa-to-serosa anastomosis. Once wound strength is sufficient to maintain the anastomosis, the NiTi Clip is passed from the body. The LapCAC is indicated for open, minimally invasive or laparoscopic procedures

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043115